



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,521	09/29/2006	Chae-Ok Yun	P10026US	1275

20529 7590 08/07/2009
THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314

EXAMINER

HILL, KEVIN KAI

ART UNIT	PAPER NUMBER
----------	--------------

1633

MAIL DATE	DELIVERY MODE
-----------	---------------

08/07/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,521	YUN ET AL.	
	Examiner	Art Unit	
	KEVIN K. HILL	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 8-12 and 14-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>October 1, 2006</u> | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

Election/Restrictions

Applicant's response to the Requirement for Restriction, filed on April 16, 2009 is acknowledged.

Applicant has elected the invention of Group III, claim(s) 7 and 13, drawn to methods of delivering a gene into cells and treating a cancer, the methods comprising administering a gene delivery system comprising a Relaxin-encoding nucleotide sequence.

Election of Applicant's invention(s) was made with traverse.

Applicant argues that the Groups I-III share a special technical feature, specifically a Relaxin-encoding nucleotide sequence to enhance a transduction efficiency of a nucleotide sequence of interest into a cell, and thus under PCT Rule 13.2, all of the presently pending claims possess unity of invention. Such a use is novel and inventive over the medical use of Relaxin disclosed by Conrad (U.S. 2002/0019349).

Furthermore, the Examiner has not set forth "an appropriate explanation" as to the existence of a "serious burden" of search for the claims of Group I-III. It is Applicant's position that there is no serious burden.

Applicants' arguments have been fully considered but are unpersuasive.

With respect to unity of invention, the structural limitations of Group I, Claim 1 is a gene delivery system comprising a Relaxin-encoded nucleic acid sequence. As stated in the prior Office Action, Conrad et al disclose a gene delivery system comprising a nucleic acid encoding Relaxin. Thus, the claim does not recite a special technical feature that contributes over the prior art. Thus, the Groups do not share a special technical feature required by PCT Rule 13.2 for unity of invention.

With respect to search burden, MPEP §803 states that "If the search and examination of all the claims in an application can be made without serious burden, the Examiner must examine them on the merits, even though they include claims to independent or distinct inventions."

Art Unit: 1633

In the instant case, Applicant appears to have overlooked the joining paragraphs on pages 3-4 of the prior Office action describing why a serious burden exists. A serious burden exists since each limitation, directed to a composition comprising a nucleic acid sequence encoding a Relaxin protein and a composition comprising a Relaxin protein to improve penetration of an undisclosed medicament into a tissue, requires a separate, divergent, and non co-extensive search and examination of the patent and non-patent literature. For instance, a search and consideration of the prior art as it relates to a composition comprising a Relaxin protein to improve penetration of an undisclosed medicament into a tissue would not be adequate to uncover prior art related to an adenovirus vector encoding a Relaxin protein.

Further, a search and examination of all the claims directed to all embodiments involves different considerations of novelty, obviousness, written description, and enablement for each claim. In view of these requirements, it is the Examiner's position that searching and examining all of the claims including limitations to a composition comprising a nucleic acid sequence encoding a Relaxin protein and a composition comprising a Relaxin protein to improve penetration of an undisclosed medicament into a tissue in the same application presents a serious burden on the Examiner for the reasons given above and in the previous Restriction Requirement.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-6, 8-12 and 14-16 are pending but withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim.

Claims 7 and 13 are under consideration.

Priority

This application is a 371 of PCT/KR05/00921 filed on March 30, 2005. Acknowledgment is made of Applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Acknowledgment is made of Applicant's claim for foreign priority based on an application filed in The Republic of Korea on March 30, 2004. It is noted, however, that

Art Unit: 1633

Applicant has not filed a certified copy of the KR 10-2004-0021601 application as required by 35 U.S.C. 119(b).

Information Disclosure Statement

Applicant has filed Information Disclosure Statements on October 1, 2006 that have been considered. The signed and initialed PTO Forms 1449 are mailed with this action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

1. **Claims 7 and 13 are rejected under 35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The claims are dependent, directly or indirectly, upon non-elected compositions. Thus, it is unclear what composition is to be administered to the patient as per the instantly claimed methods. It would be remedial to draft the claims in independent form.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the Applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the Applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Art Unit: 1633

2. **Claims 7 and 13 are rejected under 35 U.S.C. 102(b) and 35 U.S.C. 102(e)** as being anticipated by Hirsch et al (U.S. 2003/0003583).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP §201.15.

Hirsch et al disclose a method of delivering a gene into cells for the treatment of cancer [0151], the method comprising the use of an adenoviral gene delivery system [0019], wherein the gene may encode Relaxin [0140].

Conclusion

3. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to KEVIN K. HILL whose telephone number is (571)272-8036. The Examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Joseph T. Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin K. Hill/

Examiner, Art Unit 1633